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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	8

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/927,995	REYES, JOE	
	Examiner	Art Unit	
	Shaojia A Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *10-11 and 18--37* is/are pending in the application.

4a) Of the above claim(s) *19 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,11,18 and 21-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on May 23, 2003 in Paper No. 7 wherein claims 1-9 and 12-17 are cancelled, and claims 10-11 have been amended, and claims 21-37 are newly submitted.

Currently, claims 10-11 and 18-37 are pending in this application.

It is noted that claims 19-20 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species (see Applicant's election in Paper No. 5, submitted January 3, 2003), of record in the previous Office Action dated March 26, 2003 in Paper No. 6.

Claims 10-11, 18 and 21-37 are examined on the merits herein.

Applicant's amendment (amending claim 11) with respect to the objection of claim 11 for minor informalities of record stated in the Office Action dated March 26, 2003 have been fully considered and are found persuasive. Therefore, this objection is withdrawn.

Applicant's amendment filed on May 23, 2003 in Paper No. 7 with respect to the rejection of claims 10-18 made under 35 U.S.C. 112 second paragraph for the use of the indefinite expressions of record stated in the Office Action dated March 26, 2003 have been fully considered and found persuasive to remove the rejection since indefinite expressions have been deleted from the claims. Therefore, the said rejection is withdrawn.

The following is new rejection(s) necessitated by Applicant's amendment filed on May 23, 2003 in Paper No. 7.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-11 and 18 as amended now are rejected under 35 U.S.C. 112, first paragraph, as, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment filed on May 23, 2003 in Paper No. 7 with respect to amended claims 10-11 and 18 has been fully considered but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for "A composition derived from products found in nature". This recitation "A composition derived from products found in nature" is not found in the original specification.

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-11 and 18 as amended now are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the particular compound for driving blood flow to the penis, the particular aphrodisiac, the particular testosterone production compound for increasing natural production of testosterone, the particular heightening compound which heightens sexual arousal, function and performance disclosed in the specification (see page 12 of the specification herein) in composition herein, does not reasonably provide enablement for the employment any compounds for driving blood flow to the penis, any aphrodisiacs, the particular testosterone production compounds for increasing natural production of testosterone, any heightening compounds which heightens sexual arousal, function and performance recited in the claims herein, for the same reasons of record stated in the Office Action dated March 26, 2003 in Paper No. 6.

These recitations, "a vasoactive compound", "a testosterone production compound for increasing natural production of testosterone", "a sperm production compound which elevates sperms production", and a "heightening compound which heightens sexual arousal, function and performance" and other similar recitations in claim 11, are seen to be merely functional language.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to a composition for boosting the libido of an individual.

The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The instant claims are deemed very broad since the broadest claim (i.e., claim 10) reads on any compounds for driving blood flow to the penis and any aphrodisiacs employed in the composition herein.

The amount of direction or guidance presented:

Functional language at the point of novelty, as herein employed by Applicants, is admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC, 1997) at 1406: stating this usage does "little more than outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". The CAFC further clearly states that "[A] written description of an invention involving a

chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials" at 1405(emphasis added), and that "It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus.." at 1406 (emphasis added).

In the instant case, "a vasoactive compound", "a testosterone production compound for increasing natural production of testosterone", "a sperm production compound which elevates sperms production", and a "heightening compound which heightens sexual arousal, function and performance" and other similar recitations in claim 11, recited in the instant claims are purely functional distinction. Hence, these functional recitations read on any compounds that might have the recited functions. However, the specification merely provides one particular compound for each kind of functional compounds for the composition in claims 10-18 (the elected invention) (see page 12 of the specification).

Thus, Applicants functional language at the points of novelty fails to meet the requirements set forth under 35 U.S.C. 112, first paragraph. Claims employing functional language at the exact point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life

of the patent of the limited of monopoly asserted" (*General Electric Company v. Wabash Appliance Corporation et al. supra*, at 468).

The predictability or unpredictability: the instant claimed invention is highly *unpredictable* as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art cannot fully described genus, visualize or recognize the identity of the members of the genus, by structure, formula, or chemical name, of the claimed subject matter, as discussed above in *University of California v. Eli Lilly and Co*. Hence, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art is unable to fully predict possible physiological activities of any compounds having claimed functional properties in the pharmaceutical compositions herein.

Moreover, one of skill in the art would recognize that it is highly unpredictable in regard to therapeutic effects, side effects, and especially serious toxicity that may be generated by drug-drug interactions when and/or after administering to a host (e.g., a male) the ***combination*** of any compounds represented by "a vasoactive compound", "a testosterone production compound for increasing natural production of testosterone", "a sperm production compound which elevates sperms production", and a "heightening compound which heightens sexual arousal, function and performance" and other similar

recitations in claim 11, which may encompass more than a thousand compounds. See text book "Goodman & Gilman's The Pharmacological Basis of Therapeutics" regarding possible drug-drug interactions (9th ed, 1996) page 51 in particular. This book teaches that "The frequency of significant beneficial or adverse drug interactions is unknown" (see the bottom of the left column of page 51) and that "Recognition of beneficial effects and recognition of and prevention of adverse drug interactions require a thorough knowledge of the intended and possible effects of drugs that are prescribed" and that "The most important adverse drug-drug interactions occur with drugs that have serious toxicity and a low therapeutic index, such that relatively small changes in drug level can have significant adverse consequences" (see the right column of page 51) (emphases added). In the instant case, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art is unable to fully predict possible adverse drug-drug interactions occurring with many combinations of any compounds having claimed functional properties in the pharmaceutical compositions herein to be administered to a host. Thus, the teachings of the book clearly support that the instant claimed invention is highly unpredictable.

The presence or absence of working examples and the quantity of experimentation necessary:

As discussed above, only one particular compound for each kind of functional compounds employed in the composition herein is disclosed in the specification. Moreover, it is noted that the specification fails to provide working examples, i.e., testing results or data to demonstrate the instant compositions (different combinations of the

claimed compounds) to be administered to a host, i.e., a male, in treating for boosting the libido and/or treating sexual dysfunction in a male.

Thus, the specification fails to provide sufficient support of the broad use of any compounds having those functions recited in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of any compounds having those functions recited in the instant claims suitable to practice the claimed invention.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, the case *University of California v. Eli Lilly and Co.* (CAFC, 1997) and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in *undue experimentation* to test all compounds encompassed in the instant claims and their combinations employed in the claimed compositions to be administered to a host, with no assurance of success.

Applicant's remarks filed on May 23, 2003 in Paper No. 7 with respect to the rejection of claims 10-18 made under 35 U.S.C. 112, first paragraph, for lack of scope of enablement of record stated in the Office Action dated March 26, 2003 have been fully considered but are not deemed persuasive as to the scope of enablement of the instant

claims. These remarks are believed to be adequately addressed by the rejection presented above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-11 and 18 as amended now are rejected under 35 U.S.C. 102(b) as being anticipated by the Chinese herbal composition "dzan yu dan" (A Handbook of Chinese Healing Herbs, page 243-244, of record in the previous Office Action March 26, 2003).

The particular Chinese herbal composition, "dzan yu dan", for treating impotence and/or infertility including erectile dysfunction in man comprising "a vasoactive compound", and at least one compound selected from the group consisting essentially of "a testosterone production compound for increasing natural production of testosterone", "a sperm production compound which elevates sperms production", a "heightening compound which heightens sexual arousal, function and performance", "a boosting compound to boost energy and stamina", "a neurotransmitter affecting compound which intensifies neurotransmitter pleasure" and a sexual power compound which increases sexual reproductive powers". The compounds from nature in this particular Chinese herbal composition are known to inherently have functions recited in

the instant claims including enhancing sexual performance, with a pharmaceutical acceptable carrier (i.e., water) in an orally administrable form (see page 243-244, in particular the ingredients at page 244).

Thus, this herbal composition, "dzan yu dan" anticipates the claimed invention.

Claims 10-11 and 18 as amended now are rejected under 35 U.S.C. 102(b) as being anticipated by the Chinese herbal composition "wu dze tang" (A Handbook of Chinese Healing Herbs, of record in the previous Office Action March 26, 2003).

The particular Chinese herbal composition, "wu dze tang" for treating impotence and/or infertility in man including erectile dysfunction and low sperm count comprising "a vasoactive compound", and at least one compound selected from the group consisting essentially of "a testosterone production compound for increasing natural production of testosterone", "a sperm production compound which elevates sperms production", a "heightening compound which heightens sexual arousal, function and performance", "a boosting compound to boost energy and stamina", "a neurotransmitter affecting compound which intensifies neurotransmitter pleasure" and a sexual power compound which increases sexual reproductive powers". The compounds from nature in this particular Chinese herbal composition are known to inherently have functions recited in the instant claims including enhancing sexual performance, with a pharmaceutical acceptable carrier (i.e., water) in an orally administrable form (see page 244-245, in particular the ingredients at page 244-245).

Thus, this herbal composition, "wu dze tang" anticipates the claimed invention.

Claims 10-11 and 18 as amended now are rejected under 35 U.S.C. 102(b) as being anticipated by the Chinese herbal composition "mi jing tang" (A Handbook of Chinese Healing Herbs, page 246-247, of record in the previous Office Action March 26, 2003).

The particular Chinese herbal composition, "wu dze tang" for treating impotence and/or infertility in man including erectile dysfunction and involuntary loss of semen and related symptoms comprising "a vasoactive compound", and at least one compound selected from the group consisting essentially of "a testosterone production compound for increasing natural production of testosterone", "a sperm production compound which elevates sperms production", a "heightening compound which heightens sexual arousal, function and performance", "a boosting compound to boost energy and stamina", "a neurotransmitter affecting compound which intensifies neurotransmitter pleasure" and a sexual power compound which increases sexual reproductive powers". The compounds from nature in this particular Chinese herbal composition are known to inherently have functions recited in the instant claims including enhancing sexual performance, with a pharmaceutical acceptable carrier in an orally administrable form (see246-247, in particular the ingredients at page 246).

Thus, this herbal composition, "mi jing tang" anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-37 (newly submitted May 23, 2003) are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherksey (5,516,516, PTO-892) and TriBex-500™ (1998, PTO-892) and ArginMax™ (1998, PTO-892) and DeLuca et al. (US 6,093,421, PTO-892).

Cherksey teaches that Muria Puama is well known to be useful in a pharmaceutical composition for its strong sexual stimulation and libido (see col.1 lines 20-37 and col.2 lines 6-7). It is also well known in Brazil or South America that Catuaba Bark in combination with Muria Puama and their effective amounts is useful in a pharmaceutical composition for increasing the libido and tonifying sexual acitivity (see attached article).

TriBex-500™, the particular composition product comprising Tribulus Terrestris (625 mg), and Avena saltiva herb (450 mg) with a pharmaceutical acceptable carrier in an orally administrable form, is known to be useful in treating sexual dysfunction and impotency and increasing libido in men and women (see the product information).

ArginMax™, the particular composition product comprising l-Arginine, American Ginseng, Korean Ginseng, vitamin E (37 IU), and other ingredients with a pharmaceutical acceptable carrier in an orally administrable form, is known to be useful in treating sexual dysfunction and impotency and increasing libido in men and women (see the product information).

DeLuca et al. teaches that androstenedione is known to be used in treating male sexual dysfunction. DeLuca et al. also teaches that a number of botanical preparations have been used to restore erectile function, including ginseng, Ginkgo biloba, yohimbine (Pausinytalia yohimbe), and muira puama (Ptychopetoalum olacoides) a South American plant. L-arginine, as a precursor of nitric oxide, is also useful in treating sexual dysfunction in men and women.

The cited prior art do not expressly disclose the employment of particular combination of the particular ingredients in a composition. The prior art does also not expressly disclose the effective amounts of the particular ingredients in a combination in a pharmaceutical composition.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the particular ingredients in a pharmaceutical composition to be administered in treating sexual dysfunction and impotency and increasing libido, and to determine and optimize the effective amounts of the particular ingredients in a pharmaceutical composition from the known effective amounts of the particular ingredients.

One having ordinary skill in the art would have been motivated to combine the particular ingredients in a pharmaceutical composition to be administered in treating sexual dysfunction and impotency and increasing libido since each of the instant ingredient or component in the composition is well known to be useful in pharmaceutical compositions for increasing the libido and treating sexual dysfunction and impotency according to the prior art. Therefore, one of ordinary skill in the art would have

reasonably expected that combining the particular ingredients known individually useful for the same purpose, i.e., increasing the libido, in a composition to be administered would improve the therapeutic effects for increasing the libido and treating sexual dysfunction and impotency in a man, and/or would produce additive therapeutic effects in treating the same. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980) regarding combination inventions. It is considered prima facie obvious to combine two active composition components into a single composition to form a third composition useful for the very same purpose.

Moreover, the teachings regarding the well known combination of Catuaba Bark and Muria Puama in Brazil or South America, and the known combination of Tribulus Terrestris and Avena saltiva herb in TriBex-500™, and the known combination of L-Arginine, American Ginseng, Korean Ginseng, and vitamin E in ArginMax™, for increasing the libido and treating sexual dysfunction have clearly provided the motivation for the instant combination in composition claimed herein.

Additionally, one of ordinary skill in the art would have found it obvious to determine and optimize the effective amounts of of the particular ingredients in a pharmaceutical composition since the effective amounts of the each particular ingredient in a pharmaceutical composition are known in the prior art. It has also been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's remarks filed on May 23, 2003 in Paper No. 7 with respect to the prior art rejections of claims 10-18 made under 35 U.S.C. 102(b) in the previous Office Action dated March 26, 2003 have been fully considered but are moot in view of the new ground(s) of rejection set forth above.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

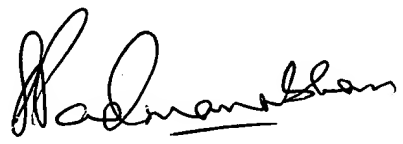
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
December 1, 2003



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

12/12/03